510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) **Submitter's name, address, telephone number, contact person:**

Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116
Gary J. Allsebrook
Regulatory Affairs Consultant
Telephone: (510) 276-2648
Fax: (510) 276-3559
Email regman1@home.com

Prepared April 19, 2000

2) **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

Combison ® C301 Diagnostic Ultrasound System and Transducers.

Classification Names:

	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) **Identification of the predicate or legally marketed device:**

Medison America, Inc believes that Combison® C301 Ultrasound system is substantially equivalent to the currently marketed Medison/Kretztechnik Combison 311 (K925354) and Combison 530D (K940942) .

4) **Device Description:**

Combison® C301:

The Combison® C301 scanner is a multiple-mode, multiple-application ultrasound imaging system. The cart-mounted console contains an ultrasound generator/receiver offering a full complement of conventional operating modes, software-based parameter controls, and recording. The selection of five transducers to be offered with the system permits a wide range of clinical applications. The various transducers adapt the system for the specific imaging tasks.

Five different models of transducers are available. In addition to the initial operational settings for each transducer preprogrammed in the system, user-customized parameter settings for each transducer may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit focusing, filtering, image enhancement processing, dynamic window curve selection. Controls are also provided to select display format (single and various combinations), to activate zoom features, and to utilize the cine loop function. Patient contact materials have been tested for biocompatibility in accordance to their intended use and are used for each individual transducer.

The Combison® C301 uses digital beamforming technology. The Combison® C301 supports a variety of Linear and Convex probes for wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions.

Probes are supported in frequencies from 3.5 MHz to 7.5 MHz. The Combison® C301 provides high quality images and various measuring functions. Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. Operating Modes of the Combison® C301 are B, B/B, B/M, and M. Management of patient history is possible by image-filing function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing. The same clinical uses were cleared for the predicate device(s), Medison/Kretztechnik Combison 311 (K925354) and Combison 530D (K940942).

5) **Intended Use**:

- Fetal - OB/GYN
- Abdominal
- Small Organs (breast, thyroid, testicle)
- Pediatric
- Neonatal Cephalic
- Trans-Vaginal
- Trans-Rectal
- Peripheral Vascular
- Cardiac

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid, and the abdominal wall.
- Pediatric scans of organs, superficial, and bony structures.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Neonatal head studies.

- Podiatry scans of superficial structures including muscles, tendons and bones.
- General cardiac studies in adults.
- Prostate, bladder and rectum visualization.

6) **Technological Characteristics:**

This device operates identical to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode images. Scanhead patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:

I_{SPTAd}	720 mW/cm2	(Maximum)
TIS/TIB/TIC	0.0 – 4.0	(Range)
MI	1.9	(Maximum)

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2000

Medison Co., Ltd.
c/o Ms. Carole Stamp
TÜV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K002491
Combison 301 PW Diagnostic Ultrasound System
Regulatory Class: II
21 CFR §892.1550/Procode: 90 IYN
21 CFR §892.1560/Procode: 90 IYO
Dated: August 11, 2000
Received: August 14, 2000

Dear Ms. Stamp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Combison 301 PW Ultrasound System, as described in your premarket notification:

WAW 4/5B Abdominal Sector Probe
WIW 17.5AP Endocavity Sector Probe
IR 4-8 Endocavity Sector Probe
NW 17.5B/C Small Part Sector Probe
ERW 7/10AK Transrectal Sector Probe

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Section 4.3 INDICATIONS FOR USE

Ultrasound Device Indications Statement

510(k) Number:
Device Name: **Combison 301 PW Ultrasound System**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B-M B-D)	Other (Specify)
Opthalmic										
Fetal		N	N	N					N	Note 2
Abdominal		N	N	N					N	Note 2
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric		N	N	N					N	Note 2
Small Organ		N	N	N					N	Note 1 Note 2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal		N	N	N					N	Note 2
Trans-Vaginal		N	N	N					N	Note 2
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		N	N	N					N	
Laparascopic										
Muscular-Skeletal Conventional		N	N	N					N	Note 2
Muscular-Skeletal Superficial										
Others (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Note 1: Small Organ: breast, thyroid, testicles, lymph-nodes, salivary gland and pediatric patients
Note 2: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002491

√Prescription Use (per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number:
Device Name: **Combison 301 PW Ultrasound System**
Transducer: **WAW 4/5B Abdominal Sector Probe**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B– M B– D)	Other (Specify)
Opthalmic										
Fetal		N	N	N					N	Note 2
Abdominal		N	N	N					N	Note 2
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric		N	N	N					N	Note 2
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Note 2: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002491

✓ Prescription Use (per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number:
Device Name: Combison 301 PW Ultrasound System
Transducer: NW 17.5B/C Small Part Sector Probe

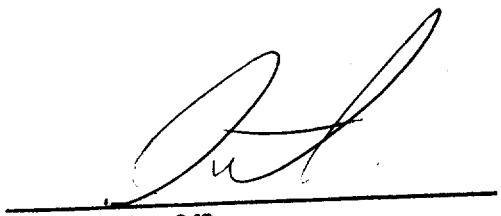
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B– M B–D)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric		N	N	N					N	Note 2
Small Organ		N	N	N					N	Note 1 Note 2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		N	N	N					N	
Laparascopic										
Muscular-Skeletal Conventional		N	N	N					N	Note 2
Muscular-Skeletal Superficial										
Others (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Note 1: Small Organ : breast, thyroid, testicles, lymph-nodes, salivary gland and pediatric patients
Note 2: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K005491

Ultrasound Device Indications Statement

510(k) Number:
Device Name: **Combison 301 PW Ultrasound System**
Transducer: **WIW 17.5AP Endocavity Sector Probe**

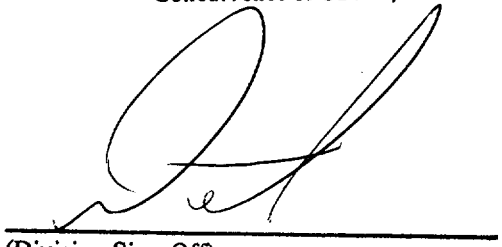
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B– M B–D)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal		N	N	N					N	Note 2
Trans-Vaginal		N	N	N					N	Note 2
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Note 2: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002491

✓ Prescription Use (per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number:
Device Name: Combison 301 PW Ultrasound System
Transducer: ERW 7/10AK Transrectal Sector Probe

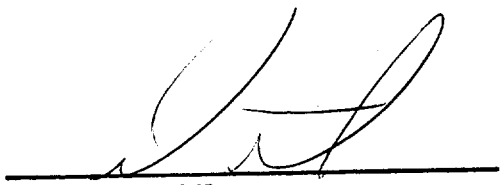
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B– M B– D)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal		N	N	N					N	Note 2
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Note 2: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)



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510(k) Number K002491

✓Prescription Use (per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number:
Device Name: Combison 301 PW Ultrasound System
Transducer: IR 4-8 Endocavity Sector Probe

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B– M B– D)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal		N	N	N					N	Note 2
Trans-Vaginal		N	N	N					N	Note 2
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

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